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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/708,881	03/30/2004	Darrel Brodke	101896-0244	2880
21125	7590	08/23/2007	EXAMINER	
NUTTER MCCLENNEN & FISH LLP			RAMANA, ANURADHA	
WORLD TRADE CENTER WEST			ART UNIT	PAPER NUMBER
155 SEAPORT BOULEVARD				
BOSTON, MA 02210-2604			3733	
MAIL DATE	DELIVERY MODE			
08/23/2007	PAPER			

**Please find below and/or attached an Office communication concerning this application or proceeding.**

The time period for reply, if any, is set in the attached communication.

<b>Office Action Summary</b>	Application No.	Applicant(s)
	10/708,881	BRODKE ET AL.
	Examiner	Art Unit
	Anu Ramana	3733

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --  
**Period for Reply**

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

#### **Status**

- 1) Responsive to communication(s) filed on 25 May 2007.
- 2a) This action is FINAL.                            2b) This action is non-final.
- 3) Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

#### **Disposition of Claims**

- 4) Claim(s) 1-30 is/are pending in the application.
- 4a) Of the above claim(s) \_\_\_\_\_ is/are withdrawn from consideration.
- 5) Claim(s) \_\_\_\_\_ is/are allowed.
- 6) Claim(s) 1-30 is/are rejected.
- 7) Claim(s) \_\_\_\_\_ is/are objected to.
- 8) Claim(s) \_\_\_\_\_ are subject to restriction and/or election requirement.

#### **Application Papers**

- 9) The specification is objected to by the Examiner.
- 10) The drawing(s) filed on 3/30/04 is/are: a) accepted or b) objected to by the Examiner.  
 Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).  
 Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

#### **Priority under 35 U.S.C. § 119**

- 12) Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
  - a) All    b) Some \*    c) None of:
    1. Certified copies of the priority documents have been received.
    2. Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.
    3. Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

\* See the attached detailed Office action for a list of the certified copies not received.

#### **Attachment(s)**

- 1) Notice of References Cited (PTO-892)
- 2) Notice of Draftsperson's Patent Drawing Review (PTO-948)
- 3) Information Disclosure Statement(s) (PTO/SB/08)  
 Paper No(s)/Mail Date \_\_\_\_\_.
- 4) Interview Summary (PTO-413)  
 Paper No(s)/Mail Date. \_\_\_\_\_.
- 5) Notice of Informal Patent Application
- 6) Other: \_\_\_\_\_.

## DETAILED ACTION

### *Petition to Correct Inventorship*

The petition to correct inventorship under 37 CFR 1.48(a) has been approved.

### ***Claim Rejections - 35 USC § 103***

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

Claims 1-2, 6-8, 10-12, 14-17, 21-22 and 25-30 are rejected under 35 U.S.C. 103(a) as being unpatentable over Shadduck (US 6,503,251) in view of Ballintyn et al. (US 5,584,836).

Shadduck discloses a fixation screw having a shank with a constant minor diameter, a distal portion with a minor diameter that decreases in a proximal-to-distal direction, opposed first and second helical threads, and a constant thread depth (Figs. 6 and 7, col. 4, lines 21-67, col. 5, lines 34-59 and col. 8, lines 19-40).

Shadduck discloses all elements of the claimed invention except for a separate head.

Ballintyn et al. teach that a screw made of a bioabsorbable material is provided with a head having a recess for receiving an insertion tool to reduce shear stress and limit shear failure to the vicinity of the head of the screw (col. 1, lines 40-54).

Accordingly, it would have been obvious to one of ordinary skill in the art at the time the invention was made to have provided the Shadduck screw with a head, as taught by Ballintyn et al., to limit shear failure to only the head of the screw.

Claims 3-5, 9, 13, 18-20 and 23-24 are rejected under 35 U.S.C. 103(a) as being unpatentable over Shadduck (US 6,503,251) and Ballintyn et al. (US 5,584,836), further in view of Schlapfer et al. (US 6,585,740).

The combination of Shadduck and Ballintyn et al. discloses all elements of the claimed invention except for the claimed ranges of lengths and the pitch.

Schlapfer et al. teach optimizing the pitch and length of a screw for improved biological anchoring (col. 4, lines 7-33 and col. 5, lines 43-56).

Accordingly it would have been obvious to one of ordinary skill in the art at the time the invention was made to have optimized the pitch and length of the Shadduck screw, as taught by Schlapfer et al., for improved biological anchoring.

It would have been obvious to one having ordinary skill in the art at the time the invention was made to have provided a pitch of 6 mm, since it has been held that discovering an optimum value of a result effective variable involves only routine skill in the art. *In re Boesch*, 617 F.2d 272, 205 USPQ 215 (CCPA 1980).

It would have been obvious to one having ordinary skill in the art at the time the invention was made to have provided lengths in a range of 20 mm to 100 mm, since it has been held that where the general conditions of a claim are disclosed in the prior art, discovering the optimum or workable ranges involves only routine skill in the art. *In re Aller*, 105 USPQ 233.

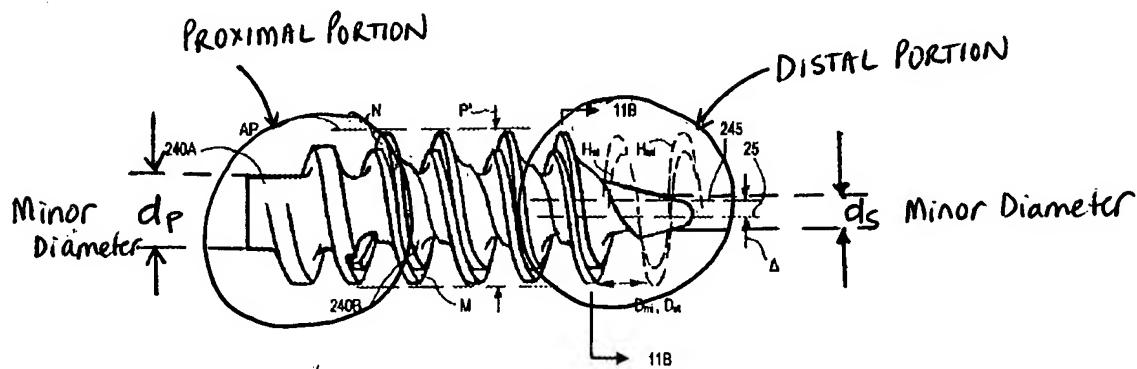
### ***Response to Arguments***

Applicants' arguments submitted under "REMARKS" in the response filed on May 25, 2007 have been fully considered.

Applicants' arguments with respect to the rejections of claims 1-2, 6-8, 10-12, 14-17, 21-22 and 25-30 as being unpatentable over Shadduck in view of Ballintyn et al. are not persuasive for the following reason.

Shadduck discloses a shank having a proximal portion with a constant minor diameter; a distal portion with a minor diameter that decreases in a proximal-to-distal direction; and opposed first and second helical threads that extend around at least a

portion of the proximal and distal portions of the shank; wherein the thread depth remains constant along the length of the shank. See marked up Fig. 7 from Shadduck below.



As illustrated above, at least partial revolutions of the helical threads extend around at least a portion of the proximal and distal portions.

Regarding claim 16, Shadduck discloses that the second axis could be parallel to but laterally offset from the first axis and meets the claim limitation of "approximately 180 degrees from one another."

Regarding claim 30, Applicants' arguments are not directed to claim limitations. As illustrated above, the shank of the Shadduck bone screw has a proximal portion with a constant minor diameter and a distal portion with a minor diameter that decreases in a proximal-to-distal direction.

### Conclusion

**THIS ACTION IS MADE FINAL.** Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any

extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the mailing date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Anu Ramana whose telephone number is (571) 272-4718. The examiner can normally be reached Monday through Friday between 8:00 am to 5:00 pm.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Eduardo Robert can be reached at (571) 272-4719. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

AR  
August 20, 2007

*Anuradha Ramana*  
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